

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

In re: BEECH-NUT NUTRITION
COMPANY BABY FOOD LITIGATION

This Document Relates To: No. 1:21-CV-133

ALL ACTIONS

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MEMORANDUM-DECISION and ORDER

I. INTRODUCTION

Plaintiffs bring this class action against defendant Beech-Nut Nutrition Company (“Beech-Nut” or “defendant”), a baby food manufacturer based in Amsterdam, New York. The 70-count Consolidated Amended Class Action Complaint (“CACC”), Dkt. 175, alleges breaches of warranties, fraud, negligent misrepresentations, and unlawful business practices related to the baby food products defendant sells throughout the country, which plaintiffs allege contain certain toxic heavy metals. In addition to monetary damages, plaintiffs seek: to enjoin defendant from selling any baby food unless all heavy metals are removed or it makes “full disclosure” on product labels; to prohibit defendant from selling baby food in any manner suggesting it is safe for consumption; and an order requiring defendant to engage in finished product testing to measure levels of heavy metals.

Beech-Nut moves for dismissal of the Complaint, or, alternatively, for a stay in deference to the United States Food and Drug Administration’s (the “FDA’s”) primary jurisdiction. The motion has been fully briefed, and the Court will now consider it on the basis of the parties’ submissions without oral argument.

II. BACKGROUND¹

Beech-Nut manufactures, markets, advertises, labels, distributes, and sells baby food products throughout the United States. CACC ¶ 93.

Plaintiffs bought defendant's baby food and fed it to their children. *Id.* ¶¶ 3, 85. Plaintiffs allege that defendant did not adequately test its products for, or disclose the presence of, toxic heavy metals, misrepresented to the public its products' safety, and continues to sell products with dangerous levels of toxic heavy metals. *Id.* ¶¶ 9-15.

On February 4, 2021, the United States House of Representative Committee on Oversight and Reform's Subcommittee on Economic and Consumer Policy (the "House Subcommittee") released a report titled "Baby Foods are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury" (the "Report"). CACC ¶ 4. The Report named several brands of baby food, including those sold by Beech-Nut, that contain, or have a material risk of containing, elevated levels of heavy metals, such as arsenic, lead, cadmium, and mercury. *Id.* ¶¶ 4-5. Plaintiffs allege that high levels of toxic heavy metals can be dangerous to human health and can harm developmental processes of infants and children. *Id.* ¶¶ 1-2. According to

¹ The facts are taken from the class action amended complaint and any and all documents attached to it, because for the purposes of a Rule 12(b)(6) motion, this Court must "accept as true the factual allegations of the complaint, and construe all reasonable inferences that can be drawn from the complaint in the light most favorable to the plaintiff[.]" *Anderson News, L.L.C. v. Am. Media, Inc.*, 680 F.3d 162, 185 (2d Cir. 2012).

plaintiffs, the Report also criticized defendant's safety standards for being less stringent than its competitors. *Id.* ¶ 5.

In direct response to the Report, the FDA informed the public that "testing ... shows that children are not at an immediate health risk from exposure to toxic elements in foods." Dkt. 189-2, Kiser Decl. Ex. A.² The FDA also assured the public that it "routinely monitors" levels of heavy metals in food and, if the levels pose a health risk, it will take steps to remove the affected foods from the market. *Id.*

Relatedly, on April 8, 2021, the FDA announced its "Closer to Zero: Action Plan for Baby Foods" (the "Action Plan"). Dkt. 189-2, Kiser Decl. Exs. B, E. The Action Plan is a comprehensive, multi-year strategy identifying actions the FDA will take to reduce the presence of arsenic, lead, cadmium, and mercury, which can naturally appear in baby food due to environmental factors. *Id.*, Exs. B, C, E. The Action Plan has four specific stages, which include: (1) evaluating the scientific basis for action levels (maximum allowable levels) for arsenic, lead, cadmium, and mercury, including establishing an interim reference level for certain toxic elements as appropriate; (2) proposing action levels for certain elements in categories of baby foods and other foods commonly eaten by babies and young children;

² The parties agree that the Court may take judicial notice of these exhibits. Moreover, on a primary-jurisdiction motion, "matters outside the pleadings are properly considered." See *Canale v. Colgate-Palmolive Co.*, 258 F. Supp. 3d 312, 324 n.11, 326 (S.D.N.Y. 2017).

(3) consulting with stakeholders regarding proposed action levels; and
(4) finalizing those levels. *Id.*, Ex. E. The FDA has already imposed deadlines for itself to finalize certain action levels – by April 2024, it will finalize levels for lead and propose action levels for arsenic, with cadmium and mercury consideration and decisions to follow. *Id.*

On September 29, 2021, the House Subcommittee released a follow-up report (the “Supplemental Report”) entitled “New Disclosures Show Dangerous Levels of Toxic Heavy Metals in Even More Baby Foods.” CACC ¶ 6. The Supplemental Report detailed findings by public health officials from the State of Alaska in June of 2021 and explained that officials found high levels of inorganic arsenic in Beech-Nut’s Rice Cereal products. *Id.* ¶ 7. This led defendant to recall certain rice cereal products. *Id.* Plaintiffs allege that defendant’s recall was incomplete and that it continues to sell baby food products, in addition to its rice cereal products, containing dangerous levels of toxic heavy metals. *Id.* ¶¶ 8, 12-13.

On February 2, 2021, plaintiffs brought this class action against Beech-Nut. Dkt. 1. The class action complaint was consolidated and most recently amended on June 24, 2022. *See generally* CACC. On August 29, 2022, defendant moved to dismiss the Consolidated Class Action Complaint pursuant to Federal Rules of Civil Procedure (“Rule”) 8, 9, 12(b)(1), and 12(b)(6). Dkt. 189.

III. DISCUSSION

Beech-Nut first argues for dismissal, or alternatively for a stay, under the primary jurisdiction doctrine. According to defendant, the FDA, not the Court through this class action, properly has jurisdiction over the subject matter of this case (*i.e.*, the regulation of heavy metals in baby food). The Court agrees that dismissal on this ground is proper and need not consider defendant's other arguments.

The primary jurisdiction doctrine “is concerned with promoting proper relationships between the courts and administrative agencies charged with particular regulatory duties.” *Ellis v. Tribune Television Co.*, 443 F.3d 71, 81 (2d Cir. 2006) (citing *United States v. W. Pac. R.R. Co.*, 352 U.S. 59, 63 (1956)). “The doctrine’s central aim is to allocate initial decision-making responsibility between courts and agencies and to ensure that they do not work at cross-purposes.” *Id.* (citation omitted). “Recourse to the doctrine of primary jurisdiction is thus appropriate ‘whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body.’” *Id.* (citing *W. Pac. R.R. Co.*, 352 U.S. at 64). When applicable, “a court defers to the agency for advisory findings and either stays the pending action or dismisses it without prejudice,” being careful not to disadvantage either party. *Johnson v. Nyack Hosp.*, 86 F.3d 8, 11 (2d Cir. 1996).

“The rationale behind the doctrine includes a concern for maintaining uniformity in the regulation of an area entrusted to a federal agency, as well as a desire for utilizing administrative expertise.” *Ellis*, 443 F.3d at 82 (internal citations omitted). Overall, the “doctrine seeks to produce better informed and uniform legal rulings by allowing courts to take advantage of an agency’s specialized knowledge, expertise, and central position within the regulatory regime.” *Id.* (citation omitted).

In applying the primary jurisdiction doctrine, courts in the Second Circuit generally consider the following four factors: (1) whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency’s particular field of expertise; (2) whether the question at issue is particularly within the agency’s discretion; (3) whether there exists a substantial danger of inconsistent rulings; and (4) whether a prior application to the agency has been made. *Ellis*, 443 F.3d at 82–83 (citation omitted).

The Second Circuit has also noted that “[t]he court must … balance the advantages of applying the doctrine against the potential costs resulting from complications and delay in the administrative proceedings.” *Id.* at 83 (citation omitted). However, it cautions that courts should not weigh this factor too heavily, particularly because “the Supreme Court has consistently held that there are only two purposes to consider in determining whether to

apply the primary jurisdiction doctrine—uniformity and expertise,” and “the Supreme Court has never identified judicial economy as a relevant factor.” *Tassy v. Brunswick Hosp. Ctr., Inc.*, 296 F.3d 65, 68 n.2 (2d Cir. 2002) (citation omitted).

Across the country, there have been several similar cases involving various baby food manufacturers. The courts that have considered the primary jurisdiction doctrine’s applicability in these cases have reached conflicting conclusions on the issue. For instance, the Northern District of California declined to find that the FDA had primary jurisdiction over claims that “Defendants fail to disclose to consumers that the Baby Foods contain (or have a material risk of containing) Heavy Metals, perchlorate, and/or other undesirable toxins or contaminants.” *In re Plum Baby Food Litigation*, No. 4:21-cv-913 (Dkt. No. 98), ¶ 11 (N.D. Cal. Sept. 3, 2021); *id.* (Dkt. No. 125), at 2 (N.D. Cal. Jan. 12, 2022). The court reasoned that “uncertainty over how and when the FDA will act counsels against an indefinite stay.” *Id.* (Dkt. No. 125) at 2 (citing *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 760 (9th Cir. 2015)).

By contrast, the Eastern District of Virginia and a New Jersey trial court found that the FDA had primary jurisdiction over claims that baby food companies’ packaging or marketing materials failed to warn that their products contained unsafe levels of heavy metals. See *In re Gerber Prod. Co.*

Heavy Metals Baby Food Litig., 2022 WL 10197651, at *15 (E.D. Va. Oct. 17, 2022); *Kimca v. Sprout Foods, Inc.*, No. BER-L-002538-22, MTD Order at 4–7 (N.J. Super. Ct. Law Div. Aug. 17, 2022). The *Sprout Foods* court reasoned that the case would require the court to “determine what levels of heavy metals in baby foods are safe and acceptable, and whether it is misleading for foods containing certain levels of heavy metals to make true labeling statements about their contents.” *Sprout Foods*, MTD Order at 5. In the court’s view, these issues were best left to the FDA’s expertise to determine and would promote “consistency of decision making.” *Id.* Citing *Sprout Foods*, the *In re Gerber* court agreed, noting that the “scientific determination” on “what levels of Heavy Metals in baby food are safe” was “particularly within the FDA’s discretion and expertise” and reasoning that the court was unable to adjudicate whether labeling was misleading “without guidance from the FDA on the Heavy Metals’ toxicity.” *In re Gerber*, 2022 WL 10197651, at *13–14.

Upon review, the Court finds that the approach taken in *In re Gerber* and *Sprout Foods* is persuasive, and that the above factors, on balance, weigh in favor of finding the FDA has primary jurisdiction over the issues in this case.

First, resolution of plaintiffs’ claims depends on “technical and policy considerations within the FDA’s field of expertise.” *In re Gerber*, 2022 WL 10197651, at *13. Contrary to plaintiffs’ assertion that this case is a “garden

“variety” false advertising case, their claims repeatedly assert that Beech-Nut’s products are “unsafe” to consume and that it is the products’ underlying toxicity, not the label statements themselves, that cause any alleged injuries. While the issue of whether a company misled consumers may be within the conventional experience of the Court, resolving plaintiffs’ claims first requires a determination on whether the levels of heavy metals in Beech-Nut’s products is harmful, which is within the FDA’s field of expertise. Accordingly, such claims cannot be resolved unless and until the FDA determines action levels for heavy metals in baby food.

Second, food safety standards are within the FDA’s authority and discretion. Congress has delegated to the FDA the responsibility for protecting public health by ensuring the safety of the food supply, *see* 21 U.S.C. § 371, 393(b)(2)(A); 21 C.F.R. §§ 7.1 *et. seq.*, and it has authorized the FDA to regulate the false or misleading labeling of food under 21 U.S.C. § 343(a)(1). Within these bounds, the FDA has confirmed its intent to “establish reference levels for exposure to toxic elements from foods … and provide action levels … for lead, arsenic, cadmium, and mercury,” Kiser Decl. Ex. L at 11, and is presently working on its Action Plan, which identifies the steps it will take in the coming years to reduce exposure to heavy metals, *see generally id.* Exs. B, C, E. Indeed, by April 2024, the FDA plans to finalize

action levels for lead and propose action levels for arsenic, with cadmium and mercury consideration and decisions to follow. *Id.*, Ex. E.

Third, there is a substantial danger of inconsistent rulings if individual courts make determinations regarding heavy metals. As noted, sister courts have already considered nearly identical issues and reached differing conclusions. In addition to Beech-Nut, there are also presently cases proceeding against other baby food manufacturers, such as Gerber, Sprout, Plum, and Hain Celestial Group, Inc. Dismissing or staying this action until the FDA offers guidance at the federal level will help to avoid a “patchwork of decisions that vary by location, court, manufacturer, and product, resulting in different labeling standards for substantially similar baby food products produced by different manufacturers.” *In re Gerber*, 2022 WL 10197651, at *15; see also *In re KIND LLC “Healthy & All Natural” Litig.*, 209 F. Supp. 3d 689, 696 (S.D.N.Y. 2016) (“staying this action until the FDA offers guidance at the federal level would almost certainly help harmonize court rulings—an important consideration in view of the fact that ‘Congress [did] not want to allow states to impose disclosure requirements of their own on packaged food products, most of which are sold nationwide’”) (citation omitted).

Fourth, defendant appears to concede that the parties have not made any previous application to the FDA on the issues before this Court, and the

Court is not aware of any such applications. Thus, this factor weighs against finding that the FDA has primary jurisdiction.

Finally, the Court acknowledges that applying the primary jurisdiction doctrine would necessarily delay plaintiffs' case. However, not applying the doctrine to this case will also result in increased costs and complications because it will force the parties to litigate a case that forthcoming FDA pronouncements will likely render moot. Thus, although it will take time for the FDA to complete its Action Plan, this factor, to the extent that it can be afforded much weight, *see Tassy*, 296 F.3d at 68 n.2, does not decisively favor either party's position.

In sum, the weight of the *Ellis* factors, coupled with the *Gerber* and *Sprout Foods* decisions, convince the Court that the FDA has primary jurisdiction to determine whether the amount of heavy metals in baby food is harmful. Accordingly, this matter will be dismissed without prejudice in deference to the FDA's primary jurisdiction.³

IV. CONCLUSION

Therefore, it is

ORDERED that

1. Defendant's motion to dismiss is GRANTED;

³ Plaintiffs may bring a new action after the FDA finalizes action levels for the metals at issue in this litigation, or three years after the FDA's forecasted April 2024 findings for lead, whichever is earlier.

2. The Consolidated Amended Class Action Complaint is DISMISSED WITHOUT PREJUDICE;
3. The Clerk of Court is directed to enter judgment accordingly and close the file.

IT IS SO ORDERED.



David N. Hurd
U.S. District Judge

Dated: January 19, 2023
Utica, New York.